

JUL 02 2004

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITYTo:  
JANE MASSEY LICATA  
LICATA & TYRRELL  
66 E. MAIN STREET  
MARLTON, NJ 08053Docket System ☒  
Status Report ☒  
Docket Book ☒  
7/30/04 W O  
7/23/04 N P

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of Mailing  
(day/month/year)

30 JUN 2004

Applicant's or agent's file reference

UT-0040

REPLY DUE

within 1 months/days from  
the above date of mailing

International application No.

PCT/US03/02356

International filing date (day/month/year)

23 January 2003 (23.01.2003)

Priority date (day/month/year)

23 January 2002 (23.01.2002)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A01N 63/00, 65/00; C12N 5/00 and US Cl.: 435/325, 424/93.1

Applicant

UNIVERSITY OF UTAH RESEARCH FOUNDATION

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

**When?** See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also** For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.  
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 23 May 2004 (23.05.2004).

Name and mailing address of the IPEA/US

Mail Stop PCT, Attn: IPEA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
Facsimile No. (703) 305-3230

Authorized officer

Joseph T. Weitach

Telephone No. (571)

Form PCT/IPEA/408 (cover sheet)(July 1998)

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**I. Basis of the opinion****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed
- ☒ the description:  
pages 1-20, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the claims:  
pages 21 and 22, as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☐ the drawings:  
pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☐ the sequence listing part of the description:  
pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**  
These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:**

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

**5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. STATEMENT**

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1-10</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-10</u>	NO
Industrial Applicability (IA)	Claims <u>1-10</u>	YES
	Claims <u>NONE</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1-10 lack novelty under PCT Article 33(2) as being anticipated by Alfei et al.

Alfei et al. teach that CD44 positive cells are most likely the precursor cells for astrocytes. Alfi et al. teach that characterization of these cells indicate that they are important in spinal cord development and astroblast formation. Alfi describe at least two different types of CD44 positive cells indicating their importance in for tissue repair and neurogenesis in general.

Claims 1-10 lack an inventive step under PCT Article 33(3) as being obvious over Marret et al and Keller et al (US 5,874,301).

Both Marret et al and Keller et al teach a population of cells that are hyaluron positive, indicating that contain the CD44 receptor which is known to be the hyaluronate receptor (see for example Alfei et al.). Both detail characterization of the cells in vitro and in vivo. Based on the properties of the isolated cells Keller et al. teach that this cell population may have a therapeutic value and propose administering the cells in transplantation protocols into patients in need of astrocytes such as in spinal cord injury.

Claims 1-10 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Isolated population of cell types have a variety of uses, including use in transplantation methodology. In the instant case such products and methods may prove clinically useful after further characterization of the isolated cells and further development of transplantation protocols.

----- NEW CITATIONS -----

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 1-10 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because the claims are not fully supported by the description. The application, as originally filed, did not describe in enough detail the specific cells encompassed by the claims. It is noted that the claimed cells are at least CD44 positive, but many cells maintain this cell surface receptor. The disclosure fails to describe adequately other characteristics of a CD44 positive cell that provide the unique property of being capable of generating astrocytes but not oligodendrocytes. Further, the claims are drawn specifically to the CD44 positive cell and it is not clear why any CD44 positive cell would not meet the limitations of the claims. The disclosure provides one source and method of isolating CD44 cells but fails to adequately describe a cell sufficiently relative to its claimed properties wherein one could distinguish the claimed cell from any other that is CD44 positive.

WRITTEN OPINION

International application No.  
PCT/US03/02356

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

**TIME LIMIT:**

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.